

ASX Announcement  
31 January 2019

## Quarterly Activities & Cash Flow Report Quarter ended 31 December 2018

*Investor Call to discuss Quarterly Results and Outlook at 9:30 am AEDT, 6 February 2019*

**Sydney, Australia, 31 January 2019:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on localised treatments for patients with pancreatic and liver cancer, today released its Appendix 4C – Quarterly Cashflow report for the quarter ended 31 December 2018 (the **Quarter** or **2Q 19**). All financial results are in Australian dollars and are unaudited.

### Key highlights:

- **US FDA has confirmed that the PanCO (ex-US) clinical study safety data meets IDE requirement and the Company can now proceed to a full US pivotal study without further US patient data**
- **OncoSil's US OncoPaC-1 clinical study has now closed for recruitment with 9 patients successfully implanted**
- **A 10<sup>th</sup> patient in the PanCO clinical study has now undergone surgical resection with curative intent; the rate of resection for the PanCO study currently stands at 24%**
- **8 out of the 10 resections have reported R0 surgical margins – a strong predictor of improved survival**
- **CE Mark Certification is in the final phase of internal peer review assessment as confirmed by the Notified Body, BSI, and is approaching final CE Mark decision point.**
- **OncoSil Management remains confident of receiving a positive CE Mark decision**
- **Cash balance as at 31 December 2018 of \$13.0m**

OncoSil Chief Executive Director Daniel Kenny commented:

*"We have made excellent progress over the last quarter on multiple fronts. We are particularly excited to have reached an important milestone in the US, with the FDA confirming that the data from our non-US PanCO clinical study satisfies the safety requirements to proceed to a full pivotal study in the US under an Investigational Device Exemption (IDE). In Europe, the CE Marking review continues. It is a complex and challenging review which will take time to conclude. BSI has now confirmed that the CE Marking is in its final phase of review assessment and we remain confident of a positive recommendation."*

### **Global Pancreatic Clinical Study Programme Update**

#### **OncoPaC-1 Clinical Study**

As previously announced to the market, OncoSil Medical was granted an Investigational Device Exemption (IDE) by the US Food and Drug Administration (FDA) in July 2016. The IDE allows the device to be used in a clinical study to collect safety and effectiveness data, and the IDE was initially granted on the condition that a safety assessment be conducted based on data obtained from 20 US patients before the Company could proceed with a full pivotal study.

In subsequent discussions with the FDA, it was agreed that data could be obtained on 10 US patients and 10 patients outside the US. OncoSil Medical is pleased to announce that, during the quarter, the FDA has confirmed that the Company has successfully met the safety requirements following submission of clinical

data from the PanCO study, allowing the Company to proceed to conducting a pivotal study in the US in a larger population.

Based on this FDA feedback, OncoSil Medical has now successfully completed patient recruitment for the US OncoPaC-1 clinical study, with 9 patients enrolled, and all of these patients have now been successfully implanted with the OncoSil™ device.

### **PanCO clinical study: surgical resection outcome update**

A total of 10 patients in the PanCO clinical study were subsequently re-staged and have now undergone surgical resection with curative intent. The resection rate currently for the PanCO study is 24% based on the Per Protocol population of 42 patients, with 8 out of the 10 resections with reported R0 surgical margins, a strong predictor of improved survival.

Current evidence-based guidelines in the management of pancreatic cancer confirm the importance of achieving R0 as the principle goal of surgical resection, as negative margin status is one of the strongest favourable prognostic indicators for long term survival.

Although surgical resection rate is not a pre-specified study objective, these findings are very encouraging and represent an important clinical milestone as this suggests the potential for “down-staging” selected patients from an initially inoperable to surgically resectable state when the OncoSil™ device is used in combination with chemotherapy.

### **CE Mark application**

As previously announced to the market the Company has provided two extensive clinical and technical reports outlining the device design, clinical performance and safety of the OncoSil device to the British Standard Institute (BSI) in support of CE Marking Certification.

The first report was provided in May and the second in October when the full pre-specified Interim analysis from the PanCO study was submitted.

The OncoSil™ device is an active implantable radioactive medical device. This is the highest class category for CE Marking. It is a unique, 1<sup>st</sup> in Class therapy. By its very nature this leads to a complex, challenging and lengthy CE Mark review process.

BSI requires time to undertake the necessary due diligence of the detailed reports and to review further Q&A responses submitted by the company, as well as seeking external subject matter experts to assist in the review.

Since the submission of these reports, the Company has engaged extensively with BSI to support its review process.

BSI has also confirmed this month that our submission for CE Marking Certification is in the final phase of review assessment and approaching final CE Marking decision.

The Company remains confident of a positive CE Marking determination and will continue to keep the market informed of developments with respect to the decision.

## Corporate and Financial

During the Quarter, the Company had cash outflows from operations of \$3.1m, resulting in a cash balance as at 31 December 2018 of \$13.0m.

## Investor Conference Call

The Company will hold a conference call at **9:30 am AEDT on 6 February 2019** to discuss the Company's financial results for the Quarter and the business outlook. The Company's Chief Executive Officer and Managing Director Daniel Kenny, will host the call.

**To access the call please use the following details: Conference ID: 652412**

<b>Australian Toll Free:</b>	<b>1800 908 299</b>
Australia Local (if dialling from international location):	+61 2 9007 8048
<b>New Zealand Toll Free:</b>	0800 452 795
<b>Hong Kong Toll Free:</b>	800 968 273
<b>Singapore Toll Free:</b>	800 101 2702
<b>China Toll Free:</b>	1080 0140 1776
<b>United Kingdom Toll Free:</b>	0800 051 1453
<b>United States/Canada Toll Free:</b>	1855 624 0077

– ENDS –

Company	Media
<b>Mr Daniel Kenny</b> CEO & Managing Director E: daniel.kenny@oncosil.com.au T: +61 2 9223 3344	<b>Arthur Chan</b> WE Buchan E: arthurc@we-buchan.com M: +61 404 369 388

### About OncoSil

OncoSil Medical is a medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil™ is a targeted radioactive isotope (Phosphorous-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted four clinical studies with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil™ in the European Union (EU) is under review with commercial launch, subject to approval.

An Investigational Device Exemption (IDE) has been granted by the United States Food and Drug Administration (FDA) to conduct a clinical study of the OncoSil™ device aimed at supporting a PMA approval. Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012, 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world-wide market opportunity for OncoSil™ in pancreatic cancer exceeds \$1b.

Hepatocellular carcinoma (HCC) or liver cancer, is the 6<sup>th</sup> most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to \$1.4b by 2019.

### Forward Looking Statements

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could

be”, “on track”, or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities’ requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management’s expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil Medical is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.

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## Appendix 4C

### Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

**Name of entity**

**ONCOSIL MEDICAL LIMITED**

**ABN**

89 113 824 141

**Quarter ended ("current quarter")**

31 Dec 2018

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,594)	(3,049)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(988)	(2,536)
(f) administration and corporate costs	(416)	(756)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	53	105
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	4,209
1.8 Other (License fee)	(141)	(141)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,086)</b>	<b>(2,168)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-

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Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:	-	-
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	-	-
<b>3.</b>	<b>Cash flows from financing activities</b>	-	-
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	-	-
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of quarter/year to date	16,123	15,205
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,086)	(2,168)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>13,037</b>	<b>13,037</b>

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	13,037	16,123
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>13,037</b>	<b>16,123</b>

6. Payments to directors of the entity and their associates		Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	60
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
6.3	Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	

7. Payments to related entities of the entity and their associates		Current quarter \$A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
7.3	Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

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**8. Financing facilities available**

*Add notes as necessary for an understanding of the position*

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000

8.1 Loan facilities

8.2 Credit standby arrangements

8.3 Other (please specify)

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

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**9. Estimated cash outflows for next quarter**

**\$A'000**

9.1 Research and development

1,500

9.2 Product manufacturing and operating costs

-

9.3 Advertising and marketing

-

9.4 Leased assets

-

9.5 Staff costs

1,050

9.6 Administration and corporate costs

400

9.7 Other (provide details if material)

**9.8 Total estimated cash outflows**

**2,950**

**10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)**

**Acquisitions**

**Disposals**

10.1 Name of entity

10.2 Place of incorporation or registration

10.3 Consideration for acquisition or disposal

10.4 Total net assets

10.5 Nature of business

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**Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Sign here:



(Company Secretary)

Date: 31 January 2019

Print name: Tom Milicevic

**Notes**

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

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